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NOTICE OF ALLOWANCE AND FEE(S) DUE

23370 7590 04/10/2008

JOHN S. PRATT, ESQ
KILPATRICK STOCKTON, LLP
1100 PEACHTREE STREET
ATLANTA, GA 30309

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/10/2008

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,656	06/20/2003	Bill E. Cham	13131-0310 (44378-282108)	8075

TITLE OF INVENTION: MODIFIED IMMUNODEFICIENCY VIRUS PARTICLES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$720	$300	$0	$1020	07/10/2008

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
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or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional	YES	$720	$300	$0	$1020	07/10/2008

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHEN, STACY BROWN	1648	424-208100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 04/10/2008

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Notice of Allowability	Application No.	Applicant(s)	
	10/601,656	CHAM ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *1/16/08*.

2. ☒ The allowed claim(s) is/are *1,28-31,33-40,42-47,49-51,53 and 54*.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☒ Certified copies of the priority documents have been received in Application No. *09/311,679* .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 2/7/08
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Stacy B. Chen/
Primary Examiner, Art Unit 1648

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with John McDonald on March 31, 2008.

The application has been amended as follows:

IN THE SPECIFICATION:

Page 1, lines 5-7, delete the existing title and replace with the following:

--MODIFIED IMMUNODEFICIENCY VIRUS PARTICLES--

Page 1, lines 10-16, delete the existing paragraph and replace with the following:

-- This application is a continuation-in-part of U.S. non-provisional patent application serial number 10/311,679 filed December 18, 2002, now abandoned, which is a US national phase from PCT patent application number PCT/IB01/01099 filed June 21, 2001, which claims the benefit of Australian patent application PQ8469 filed June 29, 2000 and PCT patent application number PCT/AU00/01603 filed December 28, 2000. The present application also claims the benefit of U.S. provisional patent application serial number 60/390,066 filed June 20, 2002.--

IN THE CLAIMS:

Claims 2 and 41 have been cancelled.

Claims 1, 28, 29, 36, 42, 43, 44, 53 and 54 have been amended as set forth in the attached claim listing.

Examiner's Comment

2. The title was amended to more accurately reflect the claimed invention. The first paragraph of the specification on page 1 was amended to update the status of parent application 10/311,679, now abandoned. Claims 1, 42, 43, 53 and 54 were amended to clarify the process steps. Claim 41 was cancelled for redundancy with respect to claim 1. Accordingly, claim 42 was amended to be dependent from claim 1. Claim 44 was amended to correct claim dependency. Claims 1, 36, 53 and 54 were amended to clarify that the viral particle is immunodeficiency virus or SIV, respectively. Accordingly, claim 2 was cancelled for redundancy with respect to claim 1.

The rejection of claims 1, 2, 28-31 and 33-54 under 35 U.S.C. 102(b) as being anticipated by, or rendered obvious under 35 U.S.C. 103(a) by Barrett et al. (US 6,136,321) is withdrawn in view of the evidence in the declaration of Dr. Moiz Kitabwalla filed January 16, 2008. The declaration presents experimental evidence that shows that particles produced by Barrett's method are structurally distinct from those produced by the instant method.

Conclusion

3. Claims 1, 28-31, 33-40, 42-47, 49-51, 53 and 54 are allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

Complete Claim Listing with Examiner's Amendment

1. (Currently amended) A modified viral particle comprising at least a partially delipidated viral particle, wherein the partially delipidated viral particle is immunodeficiency virus and ~~wherein~~ the partially delipidated viral particle:

initiates a positive immune response in an animal or human;

comprises at least one exposed epitope not usually presented to an immune system of the animal or the human by a non-delipidated viral particle; and

wherein the partially delipidated viral particle is obtained by a process consisting essentially of treating a lipid-containing viral particle with an organic solvent that is not a detergent or a surfactant.

2-27. (Cancelled)

28. (Currently amended) The modified viral particle of claim [[2]] 1, wherein the immunodeficiency virus is SIV or FIV.

29. (Currently amended) The modified viral particle of claim [[2]] 1, wherein the immunodeficiency virus is HIV.

30. (Previously presented) The modified viral particle of claim 29, wherein the HIV is HIV-1 or HIV-2.

31. (Previously presented) The modified viral particle of claim 1, wherein the at least one exposed epitope is a gag, p6 gag, gp66, gp41, p27, or env epitope.

32. (Cancelled)

33. (Previously presented) The modified viral particle of claim 1, wherein the modified viral particle has a lower lipid content in a viral envelope as compared to the non-delipidated particle.

34. (Previously presented) The modified viral particle of claim 1, wherein one or more protein on, in, or near the surface of the partially delipidated viral particle is conformationally changed as compared to one or more proteins on, in, or near the surface of the non-delipidated viral particle.

35. (Previously presented) The modified viral particle of claim 1, wherein an antigenic core of the modified viral particle remains intact as compared to the non-delipidated viral particle.

36. (Currently amended) The modified viral particle of claim [[1]] 28, wherein the immunodeficiency virus is SIV and the modified viral particle retains over 90% of major protein constituents compared to the non-delipidated viral particle.

37. (Previously presented) The modified viral particle of claim 36, wherein the major protein constituents of the modified viral particle comprise gag or env proteins.

38. (Previously presented) The modified viral particle of claim 1, wherein the modified viral particle retains at least one immunoreactive protein.

39. (Previously presented) The modified viral particle of claim 38, wherein the at least one immunoreactive protein is selected from the group consisting of p24, gp41 and gp120.

40. (Previously presented) The modified viral particle of claim 39, wherein the modified viral particle comprises at least one exposed patient specific antigen that was not exposed in the non-delipidated viral particle.

41. (Cancelled)

42. (Currently amended) The modified viral particle of claim [[4]]1, wherein the treating of a lipid-containing viral particle with an organic solvent that is not a detergent or a surfactant comprises ~~the delipidation process comprises~~:

contacting the lipid-containing viral particle in a fluid with a solvent consisting essentially of [[with]] the organic solvent that is not the detergent or the surfactant and is capable of extracting lipid from the lipid-containing viral particle;

mixing the fluid and the organic solvent for a time sufficient to extract lipid from the lipid-containing viral particle;

permitting organic and aqueous phases to separate; and,

collecting the aqueous phase containing the modified viral particle with reduced lipid content wherein the modified viral particle with reduced lipid content is capable of provoking a positive immune response when administered to the animal or the human.

43. (Previously presented) The modified viral particle of claim 42, wherein the treating of a lipid-containing viral particle with an organic solvent that is not a detergent or a surfactant further comprises ~~the delipidation process further comprises~~:

contacting the aqueous phase with a de-emulsifying agent capable of removing the organic solvent; and,

separating the de-emulsifying agent and the removed organic solvent from the contacted aqueous phase.

44. (Currently amended) The modified viral particle of claim [[44]] 42, wherein the organic solvent is an alcohol, an ether, an amine, a hydrocarbon, an ester, or a combination thereof.

45. (Previously presented) The modified viral particle of claim 44, wherein the ether is C4 to C8 ether and the alcohol is a C1 to C8 alcohol.

46. (Previously presented) The modified viral particle of claim 43, wherein the de-emulsifying agent is an ether.

47. (Previously presented) The modified viral particle of claim 1, further comprising a pharmaceutically acceptable carrier.

48. (Cancelled)

49. (Previously presented) The modified viral particle of claim 1, wherein the at least one exposed epitope is an envelope protein epitope.

50. (Previously presented) The modified viral particle of claim 1, wherein the modified viral particle has a lower lipid content in a viral envelope than the lipid content in an envelope of the non-delipidated viral particle.

51. (Previously presented) The modified viral particle of claim 1, wherein the partially delipidated viral particle has an infectivity reduced by no more than 2.5 log units as compared to the non-delipidated viral particle.

52. (Cancelled)

53. (Currently amended) A modified viral particle comprising at least a partially delipidated viral particle, wherein the partially delipidated viral particle is immunodeficiency virus and ~~wherein~~ the partially delipidated viral particle:

initiates a positive immune response in an animal or a human;

comprises at least one exposed epitope not usually presented to an immune system of the animal or the human by a non-delipidated viral particle, wherein the modified viral particle comprises at least one immunoreactive protein selected from a group consisting of p24, gp41 and gp120; and

is obtained by a process consisting essentially of treating a lipid-containing viral particle with an organic solvent that is not a detergent or a surfactant.

54. (Currently amended) A modified viral particle comprising at least a partially delipidated viral particle, wherein the partially delipidated viral particle is immunodeficiency virus and ~~wherein~~ the partially delipidated viral particle:

initiates a positive immune response in an animal or a human;

comprises an envelope, wherein the envelope comprises no extrinsic detergent or surfactant molecules; and,

comprises at least one exposed epitope not usually presented to an immune system of the animal or the human by a non-delipidated viral particle, wherein the modified viral particle is SIV and retains over 90% of major protein constituents compared to the non-delipidated viral particle and the major protein constituents of the modified viral particle comprise gag or env proteins;

wherein the partially delipidated viral particle is obtained by a process consisting essentially of treating a lipid-containing viral particle with an organic solvent that is not a detergent or a surfactant.